IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

ANDREA RACHELLE CLINTON, Plaintiff, v. MENTOR WORLDWIDE LLC, Defendant.	)	Case No. 4:16-cv-319-CEJ

PLAINTIFF'S TRIAL BRIEF

COMES NOW Plaintiff Andrea Clinton and for Plaintiff's Trial Brief states as follows:

INTRODUCTION

Plaintiff, a Missouri resident, filed her complaint against Defendant Mentor Worldwide, LLC directly into MDL No. 2004, *In Re: Mentor Corp. ObTape Transobturator Sling Products Liability Litigation* in the United States District Court for the Middle District of Georgia, Columbus Division on September 20, 2012. Plaintiff's claims for negligence, strict liability – design defect, strict liability – manufacturing defect, strict liability – failure to warn, breach of implied warranty, fraudulent misrepresentation, fraudulent concealment, and negligent misrepresentation remain pending for trial in this Court following pretrial proceedings. The parties have agreed that Missouri law applies in this case.

Plaintiff sets forth the relevant law on the following legal issues likely to be disputed during trial: design and failure to warn liability, learned intermediary, admission of marketing and promotional materials, and punitive damages.

SUMMARY OF FACTS

As a direct result of the implantation of the transobturator tape, Ms. Clinton suffered severe damages and permanent injury. She developed necrotizing fasciitis of her left leg,

myonecrosis, abscesses, and necrotic muscle and soft tissue. She further endured a long hospitalization and over twenty surgical procedures to treat her conditions. These procedures were only partially successful at improving her overall condition. Ms. Clinton continues to suffer from pain, disfigurement, anxiety, and stress as a result of her ordeal.

Ms. Clinton was implanted with a defective product because Mentor failed to conduct adequate testing on the product, and once it learned of the risk of the product causing delayed and serious infections, and failed to provide adequate warnings of the risk to Ms. Clinton's physician. Mentor also failed to timely remove the product from the market after key physicians and its own employees recommended that they do so.

Medical History

Ms. Clinton underwent implantation of ObTape on December 2, 2004, for stress urinary incontinence by Dr. John Saba at Parkland Health Center. In late August to September of 2005, Ms. Clinton was hospitalized at Barnes Jewish Hospital. She was diagnosed with necrotizing fasciitis of the left leg and had a series of surgical procedures performed by several doctors. Specifically, on August 30, 2005, Dr. John Mazuski performed a debridement of skin, subcutaneous tissue, fascia and muscle of Ms. Clinton's left thigh. He noted in the operative report that she had been transferred to Barnes Jewish Hospital to the operating room by Dr. Robb Whinney on August 31, 2005 for debridement of the adductor compartment and left lower extremity fasciotomy. Dr. Bradley Freeman performed wound exploration and debridement on September 3, 2005 and on September 4th and 5th, she was returned to the operating room by Dr. Mazuski for further debridement. On September 7, 2005, Dr. Freeman performed a wound inspection and irrigation and placed a wound VAC on the left thigh. Finally, on September 10, 2005, Dr. Douglas Shuerer performed sharp incision and debridement on Ms. Clinton's left lower extremity wounds.

On November 21, 2005, Dr. Mazuski performed a flap closure of Ms. Clinton's left thigh wound. Unfortunately, in May of 2006, Ms. Clinton's thigh abscesses and necrotizing fasciitis returned. Dr. Whinney performed another surgery for incision and drainage of two left thigh abscesses. Ms. Clinton required further surgery on September 25, 2006. At that time, Dr. Freeman performed a wound exploration and debridement of a sinus tract infection in the medial thigh. She returned to Barnes Jewish Hospital for incision and drainage of a left medial thigh abscess on April 3, 2007 by Dr. Timothy Buchman.

On December 18, 2007, Ms. Clinton had right thigh exploration with incision and drainage. Six days later, on December 24, 2007, Dr. Arnold Bullock performed vaginal exploration for removal of infected transobturator tape. He wrote in his operative report that beginning nine months after the patient had the ObTape placed, "the patient has had recurring infections in her left thigh, vaginal area in the right. She was recently admitted for incision and drainage of abscess on the right thigh. The patient was noted to have purulence at the level of the vagina." Further removal of the retained transobturator tape was performed by Dr. Bullock on February 5, 2008. At that time, he also performed incision and drainage of a right groin abscess on February 27, 2008. On September of 2008, Dr. H. Henry Lai performed a left groin dissection, cystoscopy and examination under anesthesia. Dr. Lai performed the procedure, in part, to look for any retained pieces of the transobturator tape. On June 2, 2009, Ms. Clinton suffered through yet another procedure related to her ObTape complications.

Ms. Clinton continues to suffer from pain, disfigurement, anxiety, and stress as a result of her experience with Defendant's ObTape product.

Brief Product History

Mentor showed complete indifference to patient safety by failing to perform an ObTape tissue ingrowth study, switching data concerning tissue ingrowth from a different product to

ObTape and distributing the falsified data to implanting physicians throughout the United States. Mentor was warned by its own consultant regarding obvious lack of porosity of ObTape and associated risks before it was implanted in women in the United States, but failed to heed the warnings or perform timely testing. After Mentor launched ObTape in the U.S., it received additional reports from surgeons, implicating ObTape with an unacceptably high rate of erosions and serious infections, yet failed to change its Instructions for Use or warnings.

POTENTIAL LEGAL DISPUTES

Plaintiff sets forth below the relevant law on the following legal issues likely to be disputed during trial: design and failure to warn liability, learned intermediary, and admission of marketing promotional materials, and punitive damages.

I. Design and Failure to Warn Liability

In Missouri, "the primary inquiry in a design defect case is whether the product—because of the way it is designed—creates an unreasonable risk of danger to the consumer or user when put to normal use." *Nesselrode v. Executive Beechcraft, Inc.*, 707 S.W.2d 371, 382 (Mo. banc 1986) (rejecting consumer expectations test for jury instructions); *see also Newman v. Ford Motor Co.*, 975 S.W.2d 147, 152-54 (Mo. 1998) (en banc) (rejecting risk-utility balancing for jury instructions).

In a design defect case, the plaintiff makes an evidentiary showing "that the product, as designed, is unreasonably dangerous and therefore 'defective', and that the demonstrated defect caused his injuries." *Id.* at 375–76. The "heart and soul" of a strict liability design defect case is unreasonable danger and causation. *Id.* at 376. While a plaintiff must establish that a product is defective by proving that it was unreasonably dangerous as designed, he or she "is not required to show that the manufacturer or designer is at fault." *Ray v. Upjohn Co.*, 851 S.W.2d 646, 655 (Mo.App. S.D.1993); *Smith v. Brown & Williamson Tobacco Corp.*, 275 S.W.3d 748, 792 (Mo.

App. W. Dist. 2008). Missouri does not require a plaintiff to create a safer alternative design to prove a design defect claim; it is enough that plaintiff show that the design used was defective and unreasonably dangerous. *Smith v. Brown & Williamson Tobacco Corp.*, 275 S.W.3d 748, 794 (Mo.App.2008) (plaintiff need not show what alternative design should be although defendant can show difficulties with alternative designs in defense); *Rodriguez v. Suzuki Motor Corp.*, 996 S.W.2d 47, 64-65 (Mo. 1999) (en banc) (rejecting reasonable alternative design in favor of "unreasonably dangerous" instruction).

The elements of a cause of action for strict liability failure to warn are: (1) the defendant sold the product in question in the course of its business; (2) the product was unreasonably dangerous at the time of sale when used as reasonably anticipated without knowledge of its characteristics; (3) the defendant did not give adequate warning of the danger; (4) the product was used in a reasonably anticipated manner; and (5) the plaintiff was damaged as a direct result of the product being sold without an adequate warning. *Tune*, 883 S.W.2d at 13. 89 In applying these elements, Missouri law recognizes that "a product may be rendered unreasonably dangerous and therefore actionable because of the absence of a warning concerning use or misuse, or because the warning that has been given is informationally deficient." *Nesselrode v. Executive Beechcraft, Inc.*, 707 S.W.2d 371, 382 (Mo. banc 1986). Under Missouri law, the Plaintiff has no duty to propose the wording of an adequate warning to successfully prosecute a strict liability failure to warn case. *Moore*, 332 S.W.3d at 759-60.

II. Learned Intermediary

Missouri courts adhere to the learned intermediary doctrine. *See Krug v. Sterling Drug, Inc.*, 416 S.W.2d 143, 146 (Mo.1967); *see Johnston v. Upjohn Co.*, 442 S.W.2d 93, 95; *Kirsch v. Picker Intern., Inc.*, 753 F.2d 670 (8th Cir.1985); *Callahan v. Cardinal Glennon Hospital*, 863 S.W.2d 852, 860-63 (Mo.banc 1993). Missouri courts have held that in cases involving

manufacturers of prescription drugs, the manufacturer has "a duty to properly warn the doctor of the dangers involved and it is incumbent upon the manufacturer to bring the warning home to the doctor." Krug, 416 S.W.2d at 146; *see Doe v. Alpha Therapeutic Corp.*, 3 S.W.3d 404,419 (Mo. Ct. App. 1999).

The physician acts as a "learned intermediary" between the manufacturer and the patient and any warning given to the physician is deemed a warning to the patient. *Kirsch v. Picker Intern., Inc.*, 753 F.2d 670, 671 (8 h Cir.1985); *Johnston*, 442 S.W.2d at 95. The learned intermediary doctrine provides that the failure of a drug manufacturer to provide the physician with an adequate warning of the risks associated with a prescription product is "not the proximate cause of a patient's injury if the prescribing physician had independent knowledge of the risk that the adequate warnings should have communicated." *Christopher v. Cutter Laboratories*, 53 F.3d 1184, 1192 (11th Cir. 1995).

III. Admission of Marketing and Promotional Materials

Plaintiff will seek admission of marketing and promotional materials used by Mentor to sell the ObTape product, regardless of whether Plaintiff's physicians remember seeing and/or being influenced by those materials. Such evidence has clear relevance and significance to other issues in the case, demonstrating "knowledge and motive with regard to [the product's] risk and [the defendant's] failure to adequately warn about its dangers." *Barron v. Abbott Laboratories, Inc.*, ED 103508, 2016 WL 6596091, at *13 (Mo. App. E. Dist. Nov. 8, 2016) (applying Minnesota law).

IV. Punitive Damages

Under Missouri law, punitive damages may be properly submitted to the jury in a products liability case. *Rinker v. Ford Motor Co.*, 567 S.W.2d 655, 658 (Mo. App. 1978). In strict liability cases, punitive damages may be submitted if there is clear and convincing

evidence that defendants "placed in commerce an unreasonably dangerous product with actual knowledge of the product's defect." *Letz v. Turbomeca Engine Corp.*, 975 S.W.2d 155, 164–65 (Mo.App. W.D.1997); *Peters v. Gen. Motors Corp.*, 200 S.W.3d 1, 24–26 (Mo. App. W. Dist. 2006), *opinion adopted and reinstated after retransfer* (Oct. 2, 2006). Both strict liability and negligence theories require evidence "that the defendant showed a complete indifference to or conscious disregard for the safety of others." *Id.* at 165; *see also Barnett v. La Societe Anonyme Turbomeca France*, 963 S.W.2d 639, 659 (Mo.App. W.D.1997). "'Conscious disregard or complete indifference' includes situations where the person doing the act or failing to act must be conscious from the knowledge of surrounding circumstances and existing conditions, that, although lacking specific intent to injure, the person's conduct or failure to act will naturally or probably result in injury." *Peters*, 200 S.W.3d at 24-26.

Some Missouri courts have required that the "clear and convincing evidence" standard be satisfied by evidence that the defendant knew or had reason to know that there was a high degree of probability that the defendant's conduct would result in injury. *Lopez v. Three Rivers Elec. Co-op., Inc.*, 26 S.W.3d 151, 160 (Mo. banc 2000). However, in *Rinker*, there was no finding that the defendant knew or should have known of the defect at the time of manufacture; the only evidence supporting the award of punitive damages was defendant's inaction in light of a known postmarketing defect. 567 S.W.2d at 658. As a result, admission of postmarketing and post implant evidence that Mentor acted with a complete indifference to or conscious disregard for the safety of others in order to satisfy financial interests is relevant and significant to the submission of punitive damages in this case.

Plaintiff's evidence will show that Mentor had actual knowledge of the dangerous condition of the ObTape before it was implanted in Plaintiff, knowing that there was a high degree of probability that its conduct would result in injury. *See Hoover's Dairy, Inc. v. Mid-Am.*

Dairymen, Inc./Spec. Products, Inc., 700 S.W.2d 426, 437 (Mo. 1985). Further, Plaintiff will produce evidence that Mentor's inaction after Plaintiff's implant, including neglecting to or failing to warn physicians of additional risks associated with the product, was an exercise in conscious disregard for the safety of others. This evidence includes, but is not limited to, proof that Mentor rushed its product to market, ignored negative results from animal testing, committed scientific fraud, failed to heed internal safety warnings, failed to warn physicians of serious risks, and failed to timely withdraw the product from the market, ultimately disregarding patient safety for financial objectives. Such evidence of reckless conduct furnishes all required elements and justifies a punitive damages award.

Missouri courts have emphasized the significance of punitive damages in "the furthering of society's interests of punishing unlawful conduct and deterring its repetition, and punitive damages are constitutionally permissible." *Peters*, 200 S.W.3d at 24-26; *BMW of North Am., Inc. v. Gore*, 517 U.S. 559, 567, 116 S.Ct. 1589, 1595, 134 L.Ed.2d 809 (1996). Thus, punitive damages "are imposed for the purpose of punishment and deterrence." *Rodriguez v. Suzuki Motor Corp.*, 936 S.W.2d 104, 110 (Mo. banc 1996)(quoting *State ex rel. Smith v. Greene*, 494 S.W.2d 55, 60 (Mo. banc 1973)). Missouri stresses the role of the jury in determining punitive damages awards, finding a codified cap on punitive damages to be unconstitutional because the constitutional right to a jury trial includes the right to have a jury determine the amount of punitive damages. *Lewellen v. Franklin*, 441 S.W.3d 136, 150 (Mo. 2014). With this in mind, Plaintiff requests that punitive damages be submitted to the jury in this case and that the jury be given the opportunity to fairly weigh the post implant evidence as it relates to corporate knowledge and motive.

Should punitive damages be awarded in this case, they will be subject to Mo. Rev. Stat. Ann. § 537.675 (West):

> Any party receiving a judgment final for purposes of appeal for punitive damages in any case filed in any division of any circuit court of the state of Missouri shall notify the attorney general of the state of Missouri of such award, except for actions claiming improper health care pursuant to chapter 538, RSMo. The state of Missouri shall have a lien for deposit into the tort victims' compensation fund to the extent of fifty percent of the punitive damage final judgment which shall attach in any such case after deducting attorney's fees and expenses.

CONCLUSION

Plaintiff's claims for negligence, strict liability – design defect, strict liability – manufacturing defect, strict liability – failure to warn, breach of implied warranty, fraudulent misrepresentation, fraudulent concealment, and negligent misrepresentation remain pending for trial. Ultimately, Plaintiff will provide evidence at trial that Mentor knowingly, and with reckless disregard for Plaintiff's safety, sold a dangerous and defective product that ultimately caused severe and permanent injuries for Plaintiff.

Dated: December 30, 2016.

Respectfully submitted,

BLIZZARD & NABERS, LLP

s/ Edward Blizzard
Edward Blizzard (TBN: 02495000)
eblizzard@blizzardlaw.com
Katherine Cornell (TBN: 2482858)
kcornell@blizzardlaw.com
440 Louisiana Street, Suite 1710
Houston, Texas 77002
Telephone (713) 844-3750
Facsimile (713) 844-3755

s/ Douglass A. Kreis
Douglass A. Kreis (FBN: 0129704)
Aylstock, Witkin, Kreis & Overholtz, PLLC
17 E. Main Street, Ste. 200
Pensacola, FL 32502
Telephone: (850) 202-1010
Facsimile: (850) 916-7449
dkreis@awkolaw.com

Attorneys for Plaintiff

CERTIFICATE OF SERVICE

I hereby certify that on December 30, 2016, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this member case.

s/ Douglass A. Kreis
Douglass A. Kreis (FBN: 0129704)
Aylstock, Witkin, Kreis & Overholtz, PLLC
17 E. Main Street, Ste. 200
Pensacola, FL 32502
Telephone: (850) 202-1010
Facsimile: (850) 916-7449
dkreis@awkolaw.com